IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, v. RAYMOND KRAYNAK, Defendant.	No. 4:17-CR-00403 (Judge Brann)

MEMORANDUM OPINION

NOVEMBER 9, 2020

I. BACKGROUND

In 2017, Raymond Kraynak—a doctor of osteopathy who was registered by the Drug Enforcement Administration to prescribe Schedule II, III, IV, and V controlled substances—was indicted on twelve counts of unlawfully distributing and dispensing a controlled substance, in violation of 21 U.S.C. § 841(a)(1), five counts of unlawfully distributing and dispensing a controlled substance resulting death, in violation of 21 U.S.C. § 841(a)(1), and two counts of maintaining a drug-involved premises, in violation of 21 U.S.C. § 856(a)(1).[1]

In Count 13 of the indictment, Dr. Kraynak is charged with causing the death of R.C. by prescribing Alprazolam, Hydrocodone, Carisoprodol; in Count 14 with causing the death of D.H. by prescribing Oxycodone; in Count 15 with causing the death of A.K. by prescribing Oxycodone and Alprazolam; in Count 16 with causing

[1] Doc. 3.

the death of M.L. by prescribing Temazepam, Alprazolam, and Hydrocodone; and in Count 17 with causing the death of C.S. by prescribing Oxycodone, Carisoprodol, Diazepam, and Zolpidem.[2]

The Government intends to offer at trial the expert testimony of Stephen M. Thomas, M.D., who has submitted a report that outlines his expert opinion in this matter.[3] In preparing his expert report, Dr. Thomas reviewed ten boxes of Dr. Kraynak's medical records, along with autopsy reports, toxicology reports, and police reports. After reviewing those documents, Dr. Thomas offered an expert opinion as to "whether Dr. Kraynak had prescribed controlled substances to the patients reviewed for medically legitimate purposes in the usual course of his professional practice" and whether those prescriptions were the but-for cause of Decedents' deaths.[4]

Dr. Thomas concluded within a reasonable degree of medical certainty that many of the prescriptions issued by Dr. Kraynak did not have a legitimate medical purpose. Dr. Thomas first noted that his "evaluation of Dr. Kraynak's 'medical records' presented a unique set of difficulties" because "it [is] difficult to ascribe the term 'medical record' to the piles of paper that Dr. Kraynak kept as alleged

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2 *Id.* at 19. R.C., D.H., A.K., M.L., and C.S. are collectively referred to in this Memorandum as the "Decedents."

3 *See* Doc. 60 at 1-13. When discussing Dr. Thomas' opinion, the Court cites to Dr. Thomas' expert report. However, the Court also draws from Dr. Thomas' testimony offered at the *Daubert* hearing conducted on August 5, 2020.

4 *Id.* at 3.

documentation [of] his patients' medical treatments."[5] Dr. Thomas noted that those records rendered it "[im]possible to determine upon what basis any given medication dose was being utilized, [or] whether . . . it was effective, beyond the patient reporting 'some' analgesia."[6] Dr. Thomas asserted that "[t]hese concerns about the medical records are not trivial," stating:

> The documentation of history, physical examination, review of diagnostic information, the development of diagnosis, the formulation of a treatment plan, and assessment for the risk, benefits, effectiveness, and side effects of any given medical treatment is the core of legitimate medical practice. The documentation of the patient encounter is a key determinant whether the interaction occurred within the scope of the doctor-patient relationship. For example, if a physician were to meet a patient in a parking lot and hand them a prescription in exchange for money, absent a medical record, one would not doubt that the interaction had occurred outside of the scope of the doctor-patient relationship and not in the usual course of professional practice. The same applies when the location of the interaction is not a parking lot, but the physician's office. The walls of the office do not assure that the interaction was within the scope of the doctor-patient relationship. It is the medical record that performs that function. It is through the medical record that we are able to literally see into the mind of the physician, understand his motivations, intentions, logic, and thought processes in providing any treatment to any patient at any time. . . .
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> Given that modern medical therapies, especially controlled substances are fraught with risk, [it is] the medical record that allows us to evaluate whether or not the physician has adequately accounted for those risks in the scope of the doctor-patient relationship in the usual course of professional practice and in accordance with the accepted treatment principles of any responsible segment of the medical community. Absent the physician demonstrating through the medical record that the patient interactions occurred within the usual course of professional practice in the scope of the doctor-patient relationship and in accordance with the accepted treatment principles of any responsible

[5] *Id.* at 4.
[6] *Id.* at 5.

> segment of the medical community, no such presumption can be made simply because one of the individuals has a license to practice medicine and the other does not. The medical record distinguishes the practice of medicine from drug dealing. Absent medical documentation, in my opinion, the dispensing of controlled substances in type and amounts requested by patients because patients report satisfaction with the drugs is no different than any other form of drug dealing. Physicians can, should, and must exert asymmetric power and understanding in the prescribing of these potent, potentially deadly, drugs.[7]

In examining Decedents' deaths, Dr. Thomas opined that, as to R.C., "[b]ut for Dr. Kraynak's prescribing Hydrocodone to [R.C.], she would not have died."[8] Specifically, Dr. Thomas observed that, from 2005 until 2015, while prescriptions for Hydrocodone were being written for R.C., "there was *no documentation* of medical treatment."[9] "On May 2, 2015, [R.C.] was given a prescription for 120 Hydrocodone/Acetaminophen 10/325 mg tablets. She was found dead at her home on May 3, 2015. Her autopsy revealed that she had a therapeutic level of Alprazolam at 37 nanograms per ml, but high levels of Hydrocodone with its metabolites Hydromorphone and Dihydrocodeine in lower amounts. The cause of death was 'acute mixed drug toxicity,' primarily resulting from the Hydrocodone prescribed by Dr. Kraynak on May 2, 2015."[10] Dr. Thomas opined within a reasonable degree of medical certainty that Dr. Kraynak's prescriptions to R.C. were "outside of the usual course of professional practice and outside of the scope of the doctor-patient

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7 *Id.*
8 *Id.* at 6.
9 *Id.*
10 *Id.*

relationship," and were "not in accordance with the accepted treatment principles within the responsible segment of the medical community."[11] He further concluded that "[b]ut for Dr. Kraynak's prescribing Hydrocodone to [R.C.], she would not have died."[12]

With respect to D.H., although her medical records indicated a history of physical issues, "Dr. Kraynak failed to regularly apply any of the risk mitigation tools mentioned in the controlled substance treatment agreements" that D.H. had signed.[13] Thus, although OxyContin had previously been discontinued for D.H. due to safety concerns, Dr. Kraynak continued to prescribe that drug and also renewed Oxycodone prescriptions.[14] This behavior led Dr. Thomas to conclude that, not only was "Dr. Kraynak's undocumented prescribing occurring outside of the usual course of professional practice," but "the continued prescription of high-dose opioids to a woman who had a history of acute respiratory failure secondary to opioids in the setting of her morbid obesity, congenital scoliosis and breathing difficulties, chronic renal insufficiency, and anemia was unfathomable."[15]

Moreover, Dr. Thomas noted that, at the time of her death, D.H. had "an Oxycodone blood level of 796 nanograms per ml and an Oxymorphone blood level of 17.6 nanograms per ml[, which is] an expected metabolite of Oxycodone. It was

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11 *Id.*
12 *Id.*
13 *Id.* at 8.
14 *Id.*
15 *Id.*

nonetheless pharmacologically active and both of these drugs were found in concentrations approximately four times the upper end of the expected therapeutic range. These drugs were the mechanism of her death."[16] Dr. Thomas thus opined that "[b]ut for Dr. Kraynak's willful grossly negligent prescribing pattern, [D.H.] would not have died."[17]

As to A.K., Dr. Thomas noted that infrequent patient notes indicated that A.K. suffered from some knee and back pain for which Dr. Kraynak prescribed Oxycodone and Alprazolam.[18] In the autumn of 2013, A.K. entered a rehab program and "experienced a period of abstinence from his medication."[19] After A.K. completed rehab, Dr. Kraynak again prescribed him Oxycodone, despite the fact that Dr. Kraynak should have known from A.K.'s prescription history that he underwent a period of abstinence from his medications.[20] Short after this prescription was issued, A.K. was found dead; autopsy and toxicology reports reveal that Oxycodone and Alprazolam were in A.K.'s system at levels far exceeding the therapeutic range—levels that were sufficient to cause unconsciousness, depressed breathing, and death.

Dr. Thomas opined that, given A.K.'s period of abstinence, "[i]t was not surprising that [A.K.] was found dead on October 29, 2013. The reinstitution of high-

16 *Id.*
17 *Id.*
18 *Id.* at 8-9.
19 *Id.* at 9.
20 *Id.*

dose opioid analgesia after a period of abstinence with the restoration of sensitivity to the drug, is a frequent and known cause of accidental overdose and death."[21] He further opined that "Dr. Kraynak's failure to recognize that [A.K.] was at risk was not consistent with the accepted treatment principles of any responsible segment of the medi[c]al community" and his issuance of a prescription for A.K. "was completely unjustified by the medical records available, being not in accordance with the accepted treatment principles of any responsible segment of the medi[c]al community."[22] Dr. Thomas concluded that "[b]ut for Dr. Kraynak's inappropriate prescribing of high-dose Oxycodone in an irresponsible and haphazard manner to [A.K.], [A.K.] would not have died."[23]

With regard to M.L., although she suffered from degenerative changes to her lumbar spine, "[s]uch degenerative changes are common and do not necessitate high-dose opioid therapy."[24] M.L. signed a controlled substances agreement with Dr. Kraynak but, less than 18 months later, a urine drug screen "was positive for Morphine, Hydrocodone, Oxycodone, and Alprazolam"; since M.L. was not prescribed Morphine or Oxycodone, this test was a clear indicator that M.L. was abusing narcotics.[25] M.L. was sent a "boot letter"—meaning that Dr. Kraynak would discontinue treatment—but Dr. Kraynak nevertheless "continued to supply [M.L.]

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21 *Id.*
22 *Id.*
23 *Id.*
24 *Id.*
25 *Id.*

with controlled substances," including Temazepam, Alprazolam, and Hydrocodone.[26]

A toxicology report conducted after M.L.'s death revealed the presence of Hydrocodone and benzodiazepines,[27] both of which were "the proximate cause of [M.L.'s] death."[28] This information led Dr. Thomas to opine that "[t]he continued prescribing of liberal doses of opioids and benzodiazepines to a known drug abuser was not in accordance with the accepted treatment principles within the responsible segment of the medical community[, and that] [b]ut for Dr. Kraynak's profligate, irrational, and irresponsible prescribing behavior, [M.L.] would not have died."[29]

Finally, C.S. was prescribed Oxycodone and Carisoprodol for her lower back pain and, although she executed a controlled substance agreement, Dr. Kraynak took "little [action] in the way of enforcement of its directives" despite C.S.' "documented overuse of opioids."[30] For example, "[o]n April 22, 2014, Dr. Kraynak provided [C.S.] with prescriptions for 150 Oxycodone 30 mg tablets, 120 Carisoprodol 350 mg tablets, 30 Diazepam 10 mg tablets, and 30 Zolpidem (Ambien) 10 mg tablets. *Seven* (7) days later on April 29, 2014, Dr. Kraynak

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26 *Id.*
27 Temazepam and Alprazolam are types of benzodiazepines.
28 *Id.*
29 *Id.* at 10.
30 *Id.* at 11.

provided her precisely the same prescriptions in precisely the same amounts."[31] Dr. Thomas summarized Dr. Kraynak's prescription pattern for C.S. thusly:

> The callousness and malice of the controlled substance prescribing observed in this medical record was jarring. Dr. Kraynak had abundant evidence that [C.S.] was a drug abuser. He ignored it. Dr. Kraynak knew that [C.S.] was at risk for overdose, given the history of overdose that was supplied to him. He ignored it. But even if he knew nothing of the information that had been made available to him, there was no manner in which he could have believed that the prescription of 150 Oxycodone 30 mg tablets, 120 Carisoprodol 350 mg tablets, 30 Diazepam 10 mg tablets and 30 Zolpidem 10 mg tablets to the same patient [twice] within one week, could possibly have been for a medically legitimate purpose.[32]

Shortly after Dr. Kraynak issued his final prescription for C.S., C.S. "was found dead . . . from mixed substance toxicity. Her Oxycodone level was five times the upper limit of therapeutic."[33] Dr. Thomas concluded that "[b]ut for Dr. Kraynak's haphazard, irregular, malicious prescribing, [C.S.] would not have died."[34]

In March 2020, Dr. Kraynak filed a motion to exclude Dr. Thomas' expert testimony.[35] Dr. Kraynak argues that Dr. Thomas' opinion is unreliable because it is not based on (1) sufficient facts or data, (2) reliable principles and methods, or (3) reliable application of principles and methods.[36] Dr. Kraynak only contends that Dr. Thomas' opinion is unreliable as it relates to Decedents' causes of death in Counts

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31 *Id.*
32 *Id.*
33 *Id.*
34 *Id.*
35 Doc. 57.
36 Doc. 58.

13 through 17, and he does not challenge Dr. Thomas' qualifications to offer an expert opinion, or the fit of his opinion.

First, Dr. Kraynak contends that Dr. Thomas' opinion is not based on reliable facts because Dr. Thomas does not adequately explain the standards upon which he relied in assessing Dr. Kraynak's prescription behavior, meaning that "we do not know whether Dr. Thomas' technique is acceptable because he never indicates a methodology or a comparison to Dr. Kraynak's practices against any standard."[37] Moreover, Dr. Kraynak contends that Dr. Thomas reached his conclusions without the benefit of any autopsies or toxicology reports and, thus, it is nearly impossible to determine what substances caused Decedents' deaths, rendering Dr. Thomas' opinion speculative as to the cause of those deaths.[38]

Second, Dr. Kraynak asserts that Dr. Thomas' opinion is not the product of reliable principles and methods because he reached his opinion without supporting autopsies or toxicology reports to determine what drugs were in Decedents' systems and, therefore, cannot ascertain the but-for cause of their deaths.[39] He also contends that Dr. Thomas failed to account for whether Decedents had higher tolerances for the prescription drugs.[40]

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37 *Id.* at 7; *see id.* at 6-7.
38 *Id.* at 7-8.
39 *Id.* at 8-9.
40 *Id.* at 9.

Finally, Dr. Kraynak asserts that Dr. Thomas could not have reliably applied methods and principles since there were no underlying autopsies or toxicology reports to assist him, and he failed to account for alternative explanations for the deaths, including whether Decedents had underlying medical conditions and whether their drug addictions interfered with Dr. Kraynak's ability to properly treat them.[41]

In August 2020, this Court conducted a hearing on Dr. Kraynak's motion and received testimony from Dr. Thomas. In light of Dr. Thomas' testimony at the hearing and the evidence and exhibits proffered therein, Dr. Kraynak sought an opportunity to hold the hearing open so that his expert could review that evidence and then potentially reexamine Dr. Thomas; this Court granted Dr. Kraynak's request and held the matter open until October 16, 2020.[42] No motions or documents have since been filed, and the matter is now ripe for disposition. For the following reasons, Dr. Kraynak's motion will be denied.

II. DISCUSSION

Federal Rules of Evidence 702 and 703 govern the admissibility of expert testimony and set forth certain criteria for admissibility. Expanding upon those Rules, the United States Supreme Court set out the standard for admissibility of expert testimony in *Daubert v. Merrell Dow Pharm., Inc.*[43] The Court in *Daubert* delegated to district courts a "gatekeeping responsibility" under Rule 702, which

41 *Id.* at 10-11.
42 Docs. 87, 88, 89.
43 509 U.S. 579 (1993).

requires that courts determine at the outset whether an expert witness may "testify to (1) scientific knowledge that (2) will assist the trier of fact."[44] That gate-keeping function demands an assessment of "whether the reasoning or methodology underlying the testimony is scientifically valid" as well as "whether that reasoning or methodology properly can be applied to the facts in issue."[45] A district court "exercises more control over experts than over lay witnesses," since "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it."[46]

Following *Daubert*, the United States Court of Appeals for the Third Circuit cast expert admissibility determinations in light of three basic requirements: (1) qualification; (2) reliability; and (3) fit.[47] The qualification prong demands that the proffered expert possess sufficient "specialized knowledge" to testify as an expert.[48] To satisfy the reliability prong, an expert's opinion "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'"[49] The Third Circuit has set forth eight non-exclusive factors that "a district court should take into account" when deciding the reliability of expert testimony:

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44 *Id.* at 592.
45 *Id.* at 592-93.
46 *Id.* at 595 (internal quotation marks omitted).
47 *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-43 (3d Cir. 1994) ("*Paoli II*").
48 *Id.* at 741.
49 *Id.* at 742 (*quoting Daubert*, 509 U.S. at 589).

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.[50]

With regard to the fit prong, the Third Circuit explained that admissibility "depends . . . on the proffered connection between the scientific research or test result . . . and [the] particular disputed factual issues."[51]

The burden of proof for admissibility of expert testimony falls upon the party that seeks to introduce the evidence.[52] However, as the Third Circuit has emphasized, "[t]he test of admissibility is not whether a particular scientific opinion has the best foundation or whether it is demonstrably correct. Rather, the test is whether the particular opinion is based on valid reasoning and reliable methodology."[53]

> This standard is not intended to be a high one, nor is it to be applied in a manner that requires the plaintiffs to prove their case twice—they do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.[54]

District courts must always be cognizant of the fact that "[t]he analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-

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50 *Id.* at 742 n.8.
51 *Id.* at 743 (internal quotation marks omitted).
52 *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000)
53 *Id.* (internal quotation marks omitted).
54 *Id.* (internal quotation marks omitted).

examination."[55]

Judged by those standards, the Court concludes that Dr. Thomas' expert opinion is reliable.[56] First, although Dr. Kraynak asserts that Dr. Thomas' opinion is not reliable because he "never indicate[d] a methodology or a comparison to Dr. Kraynak's practices against any standard,"[57] that assertion is not correct. Dr. Thomas explained in some detail which standards he used in reaching his conclusions and discussed the various model policies, guidelines, state statutes, data, and literature upon which he relied to conclude that Dr. Kraynak's prescription practices were deficient.[58]

Second, while Dr. Kraynak contends that Dr. Thomas' methodology is unknown,[59] Dr. Thomas explained in detail his methodology at the *Daubert* hearing. First, he reviewed the medical records to determine whether Dr. Kraynak prescribed opioids for a legitimate medical purpose within the ordinary course of practice; the addled, incomplete nature of the records, along with the circumstances surrounding the prescriptions, was sufficient for Dr. Thomas to conclude that the prescriptions were not made for a legitimate medical purpose within the ordinary course of practice. Next, to determine the cause of Decedents' deaths, Dr. Thomas examined

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55 *Id.* (internal quotation marks omitted).

56 Because Dr. Kraynak does not challenge Dr. Thomas' qualifications or the fit of his opinion, the Court will not address those prongs of the *Daubert* standard in this Memorandum.

57 Doc. 58 at 7.

58 *See* Doc. 60 at 3-4.

59 Doc. 58 at 6-7.

police reports to understand the context of the deaths, along with toxicology and/or autopsy reports and the nature and timing of the prescriptions issued to Decedents by Dr. Kraynak. This information allowed Dr. Thomas to conduct a differential diagnosis to determine the most likely causes of death for Decedents. A differential diagnosis is a tool that has long been approved by the Third Circuit,[60] and there is no indication in the record—or any argument from Dr. Kraynak—that Dr. Thomas' differential diagnosis was in any way deficient or flawed. To the contrary, in conducting his differential diagnosis, Dr. Thomas reviewed Decedents' medical records, autopsy reports, and toxicology reports, "all [of which] provide significant evidence of a reliable differential diagnosis."[61]

Third, while Dr. Kraynak contends that Dr. Thomas' expert opinion is unreliable because he reached his opinion without the benefit of any autopsies or toxicology reports—meaning that Dr. Thomas could only speculate as to the but-for causes of Decedents' deaths[62]—the record undercuts this assertion. Autopsy or coroner reports are available for R.C., A.K., and C.S.,[63] and toxicology reports are available for all Decedents.[64] Thus, the absence of autopsy or toxicology reports cannot undercut the reliability of Dr. Thomas' expert opinion.

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60 *See Paoli II*, 35 F.3d at 758-59.
61 *Id.* at 758.
62 Doc. 58 at 7-11.
63 Defendant's *Daubert* Exhibits D104, D107, D110.
64 Defendant's *Daubert* Exhibits D105, D111; Government's *Daubert* Exhibits G-1, G-2, G-3.

Finally, Dr. Kraynak contends that Dr. Thomas' expert opinion is unreliable because he failed to account for whether Decedents (1) may have had different treatment considerations given that they were from "coal country," (2) had higher tolerances for the prescription drugs, (3) had underlying medical conditions, or (4) had drug addictions that interfered with Dr. Kraynak's ability to properly treat them.[65]

At the *Daubert* hearing Dr. Thomas made clear that he considered these issues. With respect to the question of whether the fact that Dr. Kraynak's patients were from "coal country" impacted his opinion, Dr. Thomas testified that it did not, since standards for issuing opioid prescriptions are national, not regional, and the physiology of medication is the same for all individuals. Dr. Thomas further noted that he had considered drug tolerances but, given how variable tolerance levels may be, such considerations ordinarily cannot be used to determine an individual's cause of death. Similarly, any underlying drug addictions did not interfere with Dr. Kraynak's ability to treat the patients, since Dr. Kraynak did not adequately follow through with processes and procedures designed to detect such addictions, such as controlled substance agreements.

With respect to Decedents' potential underlying medical issues, Dr. Thomas acknowledged that certain conditions increase the risk presented by opioids and are

[65] *Id.* at 9-11.

factors that should be considered in determining whether to issue an opioid prescription. Nevertheless, regardless of whether Decedents had any such underlying medical conditions, Dr. Thomas' conclusion that prescription medications were the but-for cause of their deaths would remain unchanged. This is so because, as Dr. Thomas testified, when an underlying condition interacts with opioids to cause an individual's death, it remains true that the opioid—not the underlying comorbidity—directly caused the individual's death, since the underlying condition would not alone have been lethal.

Importantly, this Court is only permitted to make a "preliminary assessment" of Dr. Thomas' testimony and to determine whether such testimony is "helpful[] to the trier of fact."[66] As the United States Court of Appeals for the Eighth Circuit has explained:

> As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination. Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.[67]

Information regarding the potential tolerance levels of the decedents or underlying medical conditions does not render Dr. Thomas' expert opinion "so fundamentally unsupported that it can offer no assistance to the jury."[68] Rather, Dr.

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66 *United States v. Velasquez*, 64 F.3d 844, 849-50 (3d Cir. 1995) (internal quotation marks omitted).

67 *First Union Nat. Bank v. Benham*, 423 F.3d 855, 862 (8th Cir. 2005).

68 *Id.*

Thomas accounted for those issues, and it is not within the province of the Court to determine at this stage whether he properly accounted for them. There is a sufficient basis supporting Dr. Thomas' expert opinion such that it will be helpful to the jury, and the Court therefore will leave any determination as to the relative strength of Dr. Thomas' opinion to the jury.

III. CONCLUSION

For the foregoing reasons, the Court concludes that Dr. Thomas' expert testimony is admissible. Accordingly, Dr. Kraynak's motion to exclude will be denied.

An appropriate Order follows.

BY THE COURT:

s/ Matthew W. Brann
Matthew W. Brann
United States District Judge